



EXPRESS MAIL MAILNG LABEL EV 380181801US

Docket No. 009-26-004

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Christensen, J. et al

Serial No. 09/670,735

Examiner: Sirmons, K.C.

Filed: September 27, 2000

Art Unit: 3763

Title: INFUSION PUMP WITH PRESSURE REGULATOR

MAIL STOP NON FEE (AMENDMENT)

Assistant Commissioner for Patents

P. O. Box 1450

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**AMENDMENT**

Sir:

**IN THE CLAIMS:**

Below are the claims pending in the application, including current amendments as indicated:

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1. (Currently amended) An infusion device for continuous delivery of a quantity of fluid into a living body at a substantially constant flow-rate over an extended period of time, comprising:

a variable volume storage chamber for holding the fluid, said storage chamber including means for allowing fluid to be added to the storage chamber,

a pressurizing means for the storage chamber, said pressurizing means maintaining the pressure within the storage chamber above a preselected outflow pressure,

an outflow chamber for receiving fluid from the storage chamber, said outflow chamber including means for attachment thereto of a flow restrictor means and catheter through which fluid in the outflow chamber is delivered to a patient, and

a pressure ~~regulator~~ responsive valve means located between the storage chamber and the outflow chamber, said pressure ~~regulator~~ responsive valve means functioning to maintain the fluid in the outflow chamber at the preselected outflow pressure,

said pressure ~~regulator~~ responsive valve means providing for fluid transfer from the storage chamber to the outflow chamber at a flow rate substantially equal to or greater than the flow rate out of the outflow chamber so that there is a continuous, uninterrupted and controlled volume of flow from the outflow chamber through the flow restrictor means and catheter to the patient over said extended period of time.

wherein said pressure responsive valve means comprises:

a valve attached to a flexible diaphragm such that the pressure of the fluid in the outflow chamber acts on the diaphragm to close the valve to prevent flow of fluid from the storage chamber to the outflow chamber when the pressure in the outflow chamber is elevated to the preselected outflow pressure, and

a force applying means attached to the flexible diaphragm such that the force applied acts to open the valve when the pressure in the outflow chamber is less than the preselected outflow pressure, thereby allowing fluid in the storage chamber to enter the outflow chamber and the pressure in the outflow chamber to be held at a substantially constant preselected outflow pressure.

2. (Canceled)
3. (Currently amended) The infusion device of claim 2 1 wherein the force applying means is a spring, pneumatic device, or compressed elastomeric material.
4. (Original) The infusion device of claim 1 wherein the preselected outflow pressure ranges from about 1 psi to about 10 psi with an accuracy of  $\pm 5\%$ .
- 5 (Original) The infusion device of claim 1 wherein the storage chamber has a volume ranging from 50 ml to 500 ml and the outflow chamber has volume ranging from 2 ml to 10 ml.
6. (Original) The infusion device of claim 1 wherein the pressurizing means for the storage chamber comprises an elastomeric bladder, springs, or a pneumatic system.
7. (Currently amended) An infusion device for continuous delivery of a quantity of fluid into a living body at a substantially constant flow-rate over an extended period of time, comprising:
- a variable volume storage chamber for holding the fluid, said storage chamber including means for allowing fluid to be added to the storage chamber,
  - a pressurizing means for the storage chamber, said pressurizing means maintaining the pressure within the storage chamber above a preselected outflow pressure,
  - an outflow chamber for receiving fluid from the storage chamber, said outflow chamber including means for attachment thereto of a flow restrictor means and catheter through which fluid in the outflow chamber is delivered to a patient, and
  - a pressure regulator means located between the storage chamber and the outflow chamber, said pressure regulator means functioning to maintain the fluid in the outflow chamber at the preselected outflow pressure,
  - said pressure regulator means providing for fluid transfer from the storage chamber to the outflow chamber at a flow rate substantially equal to or greater than the flow rate out of the outflow chamber so that there is a continuous, uninterrupted and controlled volume of flow from the outflow chamber through the flow restrictor means and catheter to the patient over said extended period of time
- wherein the storage chamber comprises multiple bladders.

8. (Currently amended) An infusion device for delivering a quantity of fluid into a living body at a substantially constant flow-rate over an extended period of time, comprising:

a first chamber for storing a volume of the fluid,

a second chamber operatively attached to the first chamber for receiving fluid from the first chamber,

a regulator means located between the first chamber and the second chamber, said regulator means functioning to maintain the pressure in the second chamber at a preselected outflow pressure while providing fluid transfer from the first chamber to the second chamber at a rate substantially equal to or greater than said substantial constant flow-rate into the living body from the second chamber, a pressurizing means for maintaining the pressure within the first chamber above the preselected outflow pressure,

said first chamber including fluid input means and said second chamber including means for attachment thereto of a fluid delivery tube, said fluid delivery tube including flow restrictor means through which fluid in the second chamber is delivered to a patient in an uninterrupted manner over an extended period of time.

wherein the first chamber comprises multiple storage containers.

9 (Canceled)